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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER  
COLLINS, C

ART UNIT	PAPER NUMBER
1638	8

DATE MAILED:

8/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/384,811

Applicant(s)

LEMAUX ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 1999 and 27 November 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)                      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that an examination of claims 1-8 only to the extent that they read on the elected invention is a *de facto* rejection of the claims, which is improper. This is not found persuasive because the claims were not rejected, as applicants assert, and upon further review of the claims the examiner has determined that claim 7 properly belongs in Group I, but not in Group II, and claims 1-6 and 8 would be examined with either Group. Given the election of Group I, claims 1-8 are examined, in full, as they were originally drafted, and in view of the subject matter of the claims, which is drawn to the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to transgenic barley and wheat plants in which Ac and/or Ds transposable elements are genomically integrated. However, the specification does not

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set forth what specific structural or physical features define the claimed transgenic plants. The specification only discloses transgenic barley plants containing a modified Ds element (pSP-Ds-Ubi-bar), one of two different modified Ac elements (pBS-codA-Act-UbiAc or pUC-codA-Act-AcAc), and a modified Ds element in combination with a modified Ac element. (page 4, lines 24-33 to page 5, lines 1-2; page 20, lines 8-15; page 21, lines 23-27; page 22, lines 32-33 to page 23, lines 1-12). The identity of transgenic barley and wheat plants in which Ac and/or Ds transposable elements are genomically integrated is uncertain. The structure and physical features of the claimed transgenic plants cannot be ascertained in the absence of information about the transferred nucleic acid sequence.

4. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

"The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

5. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed transgenic plants, and given the high level of unpredictability in this art with regard to what the structural and physical characteristics would be in the claimed plant containing a genomically integrated Ac and/or Ds transposable element, one skilled in the art would not have been in possession of the claimed transgenic plants at the time this application was filed.

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***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by McElroy et al. (The Plant Journal, 1997, Vol. 11, No. 1, pages 157-165.
7. Claims 9, 11 and 12 are drawn to a method of introducing a Ds element comprising an expression cassette, or a nucleic acid encoding an Ac transposase, into barley by bombardment mediated transformation.
8. McElroy et al. teach a method of introducing a Ds element comprising an expression cassette, or a nucleic acid encoding an Ac transposase, into barley by bombardment mediated transformation (page 163 Experimental Procedure and page 159, Table 1). Accordingly claims 9, 11 and 12 are anticipated by McElroy et al.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al. (Plant Physiol., 1994, Vol. 104, pages 37-48) and Bancroft et al. (Mol. Gen. Genet., 1992, Vol. 233, 449-461).
11. Claims 1-14 are drawn to methods of introducing Ac and Ds transposable elements into plants, and plants containing Ac and Ds elements integrated into their genomes.

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12. McElroy et al. teach a method of introducing a Ds element comprising an expression cassette, or a nucleic acid encoding an Ac transposase, into barley by bombardment mediated transformation (page 163 Experimental Procedure and page 159, Table 1). McElroy et al. do not teach regeneration of transgenic barley plants, plants containing Ac and Ds elements integrated into their genomes, or the use of *cod A* as a negative selectable marker.
13. Wan et al. teach bombardment mediated transformation of barley with expression cassettes containing the *bar* gene, the *uidA* gene, and the BYDVcp gene, and regeneration of transgenic barley plants (pages 37-39 *Materials and Methods*, and page 44, *Figure 7*).
14. Bancroft et al. teach a method of introducing Ac and Ds elements into *Arabidopsis*, and transgenic *Arabidopsis* plants containing Ac and Ds elements integrated into their genomes. (*Introduction of modified elements into A. thaliana* pages 451-452, *Figure 1* page 451, and *Table 1* page 452). Bancroft et al. also teach the introduction of both transposable elements into *Arabidopsis* by a sexual cross (*Transactivation of Ds by sAc* pages 452-453, and *Table 2* page 454). In addition, Bancroft et al. teach transgenic plants containing a Ds element integrated at a position to which it had transposed (Column 1, lines 3-24 page 459, and *Figure 4* page 457).
15. Because Wan et al. demonstrated successful transformation of barley and regeneration of transgenic barley plants, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to combine the method of barley regeneration as taught by Wan et al. with the method of introducing Ac and Ds elements into barley taught by McElroy et al., especially given the success of Bancroft et al of producing transgenic *Arabidopsis* containing integrated Ac and Ds elements, for the purpose of producing transgenic barley containing integrated Ac and Ds elements, without any surprising or unexplained results.

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16. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al., in view of Bancroft et al., and further in view of Perera et al. (Plant Molecular Biology, 1993, Vol. 23, pages 793-799).

17. Claims 15-16 are drawn to methods of introducing Ac and Ds transposable elements into plants using the negative selectable marker *cod A*.

18. McElroy et al. in view of Wan et al. and Bancroft et al. teach methods of introducing Ac and Ds elements into barley, as discussed *supra*. McElroy et al. in view of Wan et al. and Bancroft et al. do not teach a negative selectable marker such as *codA*.

19. Perera et al. teach the use of *cod A* as a negative selectable marker for the transformation of *Arabidopsis* plants (Abstract and page 796 Fig. 2).

20. Because Perera et al. had already successfully demonstrated the use of *cod A* as a negative selectable marker for plant transformation at the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the method taught by McElroy et al. in view of Wan et al. and Bancroft et al. and to modify it by substituting the use of *codA* as a negative selectable marker in the instant invention as an optimization of design parameters.

21. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

**Remarks**

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:15 AM -4:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*cc*  
Cynthia Collins  
December 18, 2000

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600

*Elizabeth F. McElwain*